

Johnson & Johnson

BABY PRODUCTS COMPANY

October 15, 1974

SUBJECT: Talc/Powder Safety Studies
Review Meeting - September 27, 1974

This meeting was held in the Medical Conference Room on September 27th with the following in attendance:

Mr. W.H. Ashton
Mr. G. Heinze
Dr. G. Hildick-Smith
Mr. G. Lee
Dr. G. Lord
Mr. J. Murray

Dr. W. Nashed
Dr. D.R. Petterson
Dr. B. Semple
Dr. T.H. Shelley
Dr. W.C. Waggoner

1. MRC Studies

No additional status reports have been received from MRC and Dr. Hildick-Smith agreed to get from Dr. Gilson details of what experiments are actually underway and their findings.

Dr. Lord recounted that during the June, 1974 N.I.H. meeting the MRC test dosages had been critized as being excessive.

ACTION:

After this meeting, Dr. Hildick-Smith confirmed through Dr. C. Wagner of the MRC that they were not proceeding with further talc studies, other than the chronic inhalation study underway.

2. Tenovus

Dr. Hildick-Smith suggested that he would attempt to probe the Tenovus findings by requesting from Dr. Gilson a copy of the submitted Tenovus abstract for the 1975 Edinburgh meeting. It was proposed that an inquiry to Dr. Pooley may also give us a fix on the Tenovus activities.

ACTION:

Dr. Wagner (MRC) has reported to Dr. Hildick-Smith that the Tenovus abstract indicated data to show that "talc is present in various normal and cancerous tissues of the human body, but that Tenovus indicates that the presence of talc does not necessarily mean that talc is cancer producing".

Dr. Hildick-Smith has requested Dr. Rolle to contact Dr. Pooley for any intelligence which he may have.

3. Asbestos Identification - CTFA Task Force

The analytical schemes utilizing X-ray Diffraction and DTA proposed by the Task Force were outlined. Grave concern was expressed by the meeting with the inclusion of TEM as an alternative follow-up to Optical Dispersion, if the sample fails DTA and passes Optical. Dr. Nashed stressed that the FDA is looking for practical monitoring methodology which would not require the TEM.

ACTION:

G. Lee would convene a separate meeting with Drs. Nashed and Rolle to resolve the difficulties surrounding the TEM recommendation.

4. Italian Miners Epidemiological Study

Dr. Hildick-Smith reported on the preliminary overview of the Rubino Data which dispels cancer concern associated with exposure to talc. The group was informed that Professor Rubino will deliver a preliminary paper on this study at the October 7th meeting of the Italian Society of Occupational Medicine in Turin.

Dr. Hildick-Smith is reviewing the collected data and will consider any questions raised by our committee during this detailed analysis.

ACTION:

Dr. Hildick-Smith will conduct a comprehensive review of the data.

It has been proposed that Professor Rubino give his data the following exposure.

1. Paper to be published in the Journal of the Italian Society of Occupational Medicine, February - March, 1975.

2. Paper to be submitted for publication in the U.S. Journal of Occupational Medicine.

3. Papers to be presented at the following meetings:

American Occupational Medical Association
San Francisco, April 13-17, 1975.

18th International Congress on Occupational
Health, Brighton, England, September
14-19, 1975.

4th International Symposium on Inhaled Particles
and Vapors, Edinburgh, September 22-26,
1975.

4. Summary of Rubino data will be included in a review paper to be submitted for publication by Dr. Hildick-Smith in October, 1974 to the British Journal of Industrial Health.

[Messrs. Hildick-Smith, Petterson, Waggoner and Lee will meet with Mr. L. Foster to discuss appropriate press releases covering the above presentations.

5. Battelle Inhalation Study

Dr. Lord reported the status of this study to be the following:

<u>Group</u>	<u>Exposure Days</u>	<u>Group</u>	<u>% Mortality</u>
1	30		88
2	30		95
3	30	17½ months	92
4	300	14½ months	54
5	300		55
6	Control		92
7	Control		60

Autopsies of the hamsters still indicate no treatment related deaths but slight alveolar thickening is noted.

6. NIOSH - Harvard Talc Workers Study

NIOSH has recently contacted Windsor Minerals to request a review of the workers' health records. Dr. Hildick-Smith suggested to Windsor that they engage Dr. Green as a consultant in this matter and provide a medical interface with NIOSH.

It was suggested that we also invite Dr. Green to New Brunswick to present his data and hence spur him on towards completion of his study.

7. FDA - Lovelace Aerosol Study

The Lovelace Proposal for the FDA - sponsored Aerosol Study has been presented to the CTFA for comment. It is the intention of Johnson & Johnson to input with respect to the Aerosolized Talc protocol through Dr. Paul Finkelstein who is chairman of the CTFA inter-industry subcommittee responsible for providing industry comment and informational guidance. Johnson & Johnson can provide considerable experience in talc characterization, methodology and realistic exposure dosages gained through the Battelle Study.

Dr. Petterson suggested that we consider dissuasion of FDA from conducting studies with aerosolized talc by demonstrating that commercial volumes of this product commodity were minimal and not worthy of concern.

ACTION:

G. Lee and Dr. J.E. Willson will provide informational requirements through Dr. Finkelstein.

G. Lee will convene a meeting of Messrs. Steinberg, Stites and Petterson to discuss Dr. Petterson's idea outlined above.

8. World Data Pert Chart and Strategy

Dr. Hildick-Smith presented his chart of the various talc studies and highlighted three studies which are reviewed as being contentious, namely MRC, Lovelace and Tenovus. It was proposed that we anticipate MRC's Inhalation ~~Test~~ by having Battelle present interim data at the April, 1975, San Francisco Occupational Meeting. This paper could describe the approach taken to dose calculation, the test protocol and the interim results.

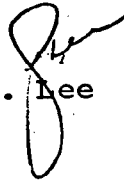
It was further proposed that Dr. Lord deliver a review paper covering the literature concerning animal talc toxicology.

Strategy-wise we should concentrate on the Frisco Meeting and the two British meetings in 1975.

ACTION:

Proposed papers will be submitted to the intended meetings.

We will add the BIBRA and Consultox studies to the original Outline of Talc Research Studies.


G. Lee

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